K021495

OCT 01 2002

**510(k) Summary** **QIVA**

This summary statement complies with 21CFR, section 807.92(c).
Date summary prepared: 1 May 2002

This premarket notification has been submitted by Pie Medical Imaging BV and covers the QIVA software package. Pie Medical Imaging is located at:

**Pie Medical Imaging BV**
**Becanusstraat 13 D**
**6216 BX Maastricht**
**The Netherlands**
**tel +31.43.3281328**
**fax +31.42.3281329**
**e-mail: pmi@pie.nl**

The contact person is: Ms. Carla de Vries, Quality Assurance Officer

The trade name is: QIVA
The common name for this type of device is:
Quantitative Intra Vascular Ultrasound Analysis Software
and the classification name is:
Image Processing System (LLZ).

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The QIVA software package is substantially equivalent to the QCU-CMS software package known under FDA number K011582.

The Quantitative Intra Vascular Analysis software offers digitization of VCR recordings of IVUS pullback examinations, semi-automatic contour detection of the lumen, vessel and stent structures in different user definable regions and quantitative analysis of the dimensions of all structures. Contours can be saved and the results of the analysis can be presented in printed reports or saved to a spreadsheet file. QIVA has been developed for Windows 2000 and NT.

The intended use of the QIVA is:

1. Digitization of VCR recordings of ICUS (Intra Coronary Ultra Sound ) or IVUS (Intra Vascular Ultra Sound) examinations of patients to the (IVUS) DICOM 3 format

2. Quantitative analysis of artery and stent dimensions.

The QIVA is substantially equivalent to the predicate device mentioned in this summary by using the same technological characteristics and intended use.

The QIVA is produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2002

Pie Medical Imaging B.V.
c/o Ms. Colleen Densmore
The Anson Group, LLC, an Aventor Company
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K021495
Trade Name: QIVA Intra Vascular Ultrasound Analysis software
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 28, 2002
Received: September 3, 2002

Dear Ms. Densmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

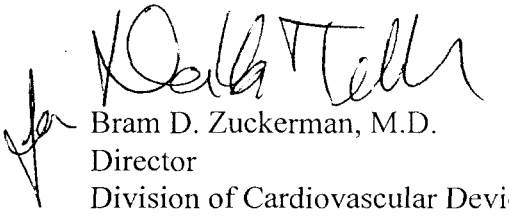
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Notification - QIVA

*INDICATION FOR USE STATEMENT* *page 1 of 1*

510(k) number (if known): K021495

Device Name: QIVA

Indications For Use:

1. Digitization of VCR recordings of ICUS (Intra Coronary Ultra Sound ) or IVUS (Intra Vascular Ultra Sound) examinations of patients to the (IVUS) DICOM 3 format

2. Quantitative analysis of artery and stent dimensions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021495

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)